UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE Y-mAbs THERAPEUTICS, INC. SECURITIES LITIGATION

23-cv-431 (AS)
MEMORANDUM OPINION AND ORDER

ARUN SUBRAMANIAN, United States District Judge:

Omar Miramontes, on behalf of a putative class of purchasers of stock in Y-mAbs Therapeutics, Inc. between October 6, 2020, and October 28, 2022, brings this securities action against Defendants Thomas Gad, Claus Juan Møller San Pedro, Vignesh Rajah, and Y-mAbs. Defendants move to dismiss. Dkt. 39. For the following reasons, Defendants' motion is granted in part and denied in part.

BACKGROUND

Y-mAbs is a clinical-stage biopharmaceutical company focused on developing cancer treatments. Am. Compl. ¶ 4, Dkt. 38. Thomas Gad founded Y-mAbs in 2015. ¶ 26. He serves as Y-mAbs's President, interim Chief Executive Officer, Head of Business Development and Strategy, and as a board member. *Id.* Claus Juan Møller San Pedro was Y-mAbs's Chief Executive Officer from June 2015 to April 2022 and the interim Chief Commercial Officer from December 2021 until January 2022. ¶ 27. Vignesh Rajah has been the company's Senior Vice President, Chief Medical Officer, and Head of Late-Stage Development since June 2020. ¶ 28.

This case concerns statements that Defendants made about one of Y-mAbs's drug candidates, I-Omburtamab ("omburtamab"). ¶ 5. Omburtamab was designed to treat pediatric patients with neuroblastoma that relapses in the central nervous system or leptomeninges (CNS/LM relapse). ¶ 33. There "are currently no FDA-approved therapies for neuroblastoma with CNS/LM relapse and [the] standard of care is not well defined." ¶ 35. The median survival duration has historically been less than one year, but it has improved over the last two decades, particularly in patients who have received craniospinal irradiation and chemotherapy. ¶ 36.

Development of omburtamab was initiated by the Memorial Sloan Kettering Cancer Center with Study 03-133. ¶ 37. Study 03-133 was a single-arm study, in which 94 patients received omburtamab, with doses varying by age. ¶ 38. Prior to receiving omburtamab, the patients had received surgery, chemotherapy, or radiation, and most patients had received all three. ¶ 39. The three-year overall survival (OS) rate was 54% of the 94 patients. ¶ 41.

Study 03-133 did not use a control group. ¶ 37. Instead, Y-mAbs sought to measure the efficacy of the drug by comparing the study's findings with clinical data published by the Central German Childhood Cancer Registry (CGCCR). ¶ 42. The CGCCR data covered patients with Stage 4 neuroblastoma from clinical trials in 1990 to 2015. *Id.* According to Miramontes, the CGCCR control group was not "fit-for-purpose" as a comparator, and differences between the two studies created a bias in favor of Study 03-133. ¶¶ 56–65.

Y-mAbs also conducted another single-arm trial, Study 101. ¶ 67. Like Study 03-133, Study 101 attempted to measure omburtamab's three-year OS rate. *Id.* In addition, Study 101 sought to measure the anti-tumor effects of omburtamab. *Id.* Study 101 initially provided limited data on patients' overall response rate (the proportion of patients who respond, at least partially, to therapy), and, according to Miramontes, "no patient in Study 101 demonstrated an unequivocal treatment response that could be definitively attributed to omburtamab." ¶¶ 69, 75.

I. Factual History

Y-mAbs sought FDA approval to distribute omburtamab through a Biologics License Application (BLA). ¶ 54. Before submitting its BLA, Y-mAbs had multiple meetings with the FDA. ¶ 76. Miramontes alleges that the FDA repeatedly expressed concerns—including on December 9, 2016, and May 18, 2017—about Study 03-133. ¶¶ 79–80. The amended complaint claims that the FDA was concerned that "the CGCCR external control data may not be fit-for-purpose as a direct comparator for the overall survival data from patients in Study 03-133 because the patient populations may not have sufficient comparability for a valid comparison." ¶ 77. The amended complaint also alleges that the FDA repeatedly stated that it needed direct evidence of the anti-tumor effect of omburtamab. *Id.*

The FDA also voiced concerns about Study 101. For example, on June 14, 2017, the FDA stated that "the proposed study was inadequate to characterize the efficacy of omburtamab." ¶ 81. And after Y-mAbs submitted the protocol for Study 101, the FDA issued an Advice Letter on December 19, 2017. ¶ 83. It expressed concern regarding how the data was interpreted. *Id.* The FDA provided a similar warning on March 26, 2019. ¶ 84. The FDA also raised concerns over the limitations of Study 03-133 during meetings on November 19, 2019, and February 25, 2020, as well as in an Advice Letter on December 12, 2019. ¶¶ 86–88.

On August 5, 2020, Y-mAbs submitted its initial BLA. ¶ 89. The FDA issued a Refusal to File (RTF) letter on October 2, 2020, indicating that the Y-mAbs BLA "did not contain substantial evidence consisting of adequate and well-controlled investigations that [omburtamab] is safe and effective for the treatment of pediatric patients with neuroblastoma that has relapsed to the CNS or LM." ¶ 90. The RTF letter also identified problems with Study 03-133 based on the lack of adequate external control data. *Id.*

On October 5, 2020, Y-mAbs issued a press release informing investors that it had received an RTF letter from the FDA, but it did not disclose the letter itself. ¶ 91. The press release stated that "[n]o additional non-clinical data have been requested or are required," "Y-mAbs is confident that it can address all points raised by the FDA," and Y-mAbs "plans to work in close dialog with the Agency in order to amend the BLA with the goal of resubmitting the BLA before the end of 2020." ¶¶ 92–94. The press release was also attached to a Form 8-K that Gad signed and that Y-mAbs filed with the SEC. ¶ 102.

During a conference call on October 6, 2020, Møller reiterated those points and stated that "[w]e remain confident that we can address all points raised by the FDA." ¶ 95. In response to a question, Møller said that he was "very surprised" about the FDA's determination, that "[w]e are going to rectify this," and that the FDA "really want to emphasize that they want to work with us on getting this successfully refiled and approved as quickly as possible." ¶¶ 96–98. Møller further stated that the FDA "requested 2 things": (1) "a different type of statistical comparison between the data from Study 03-133 and the old study" and (2) "tumor response data for patients from Study 101, where the tumor responses has been independently evaluated according to the RANO [Response Assessment in Neuro-Oncology] criteria for measuring tumor responses in the central nervous system." ¶ 100. According to Møller, "we have everything, and I have no concern that the FDA will think, 'Oh, that is not a sufficient response.' I think we are beyond that also." *Id*.

During a meeting with the FDA on November 3, 2020, the agency expressed concerns about the CGCCR external control data. ¶ 106. Three days later, on a November 6 earnings call, Møller stated that Y-mAbs was "expecting to resubmit the omburtamab BLA late 2020 or in the beginning of 2021," was "confident that it can address all points raised by the FDA," and had "resolved all the issues." ¶ 107. Møller also reported favorable results from Study 101. ¶ 109. On January 7 and 8, 2021, the FDA again told Y-mAbs that "the CGCCR external control was not fit-for-purpose due to [a] lack of granular patient-level data." ¶¶ 111–112.

During an earnings call on February 26, 2021, Møller stated that "[w]e remain confident that we can address all points raised by the FDA, including providing the requested supplementary data from Study 101." ¶ 115. Møller indicated that a new paper had become available since December 2020 with "more granularity and details," giving Y-mAbs "2 sets of historical controls." ¶ 117. One month later, the FDA "again expressed concern that insufficient information was provided to determine whether the data from CGCCR are fit-for-purpose for establishment of a robust external comparator and outlined specific deficiencies" and warned that fixing that shortcoming may require "an alternative clinical development program." ¶ 119.

On May 7, 2021, Gad stated during an earnings call that Y-mAbs intended to resubmit the BLA in the second or third quarter of 2021 and that the company "hope[d] to reach final agreement with the agency on the remaining details concerning this granularity of the data from our identified historical control groups and how we would work forward with this" in an upcoming June 1 meeting. ¶ 120. Y-mAbs did not reach an agreement with the FDA during the June 1 meeting. ¶ 121. But in a June 23 press release reporting on the meeting, Y-mAbs stated that it had "a clearer path towards the resubmission of the omburtamab BLA to the FDA" and that Y-mAbs was "aligned with the FDA on next step towards the resubmission." ¶ 122.

During an earnings call on November 5, 2021, Gad stated that "the resubmission of the omburtamab BLA is progressing well." ¶ 127. Møller stated that Y-mAbs was "aligned with the FDA on the next steps." *Id.* The next month, on December 15, Møller stated during a presentation that Y-mAbs "expect[ed] to get a green light" after a January meeting with the FDA because the

company had "put together a very strong package that should satisfy the concerns the FDA raised" in the RTF and during subsequent discussions. ¶ 129. During the January 2022 meeting, however, the FDA "stated that there was insufficient information to provide agreement on the efficacy package to support the BLA" and noted other weaknesses with Y-mAbs's external controls and reliance on Study 101. ¶ 131.

On February 11, 2022, Y-mAbs issued a press release. ¶ 133. Gad is quoted as stating that "[w]e are pleased with the outcome of the pre-BLA meeting for Omburtamab providing a clear regulatory path forward for the resubmission of the BLA." *Id*. Møller is quoted as stating that "[w]e believe that we can resubmit the Omburtamab BLA by the end of the first quarter of 2022." *Id*. Y-mAbs held an earnings call two weeks later, during which Gad stated that "[t]he resubmission of omburtamab BLA is progressing as planned. We held a pre-BLA meeting with the FDA in January, which confirmed our path towards a BLA resubmission in March." ¶ 137. Møller stated that Y-mAbs was "very pleased to be aligned with the FDA on the next step." *Id.* In response to a question, Møller claimed that the company had "all the information that we need" and was "not waiting for additional stuff to come in." ¶ 138. He further stated that the FDA wanted to understand "to which degree they can verify the historical control data in the central German cancer registry in Cologne, but that's not something that is holding up the submission of the BLA filing." *Id.*

On March 25, 2022, "Y-mAbs provided additional detail regarding the audit process for the CGCCR external control dataset to FDA and stated they welcomed the opportunity to discuss the proposal in a teleconference the following week." ¶ 140 (internal quotation marks omitted). On March 29, the FDA agreed to follow up within 30 days. ¶ 141. But Y-mAbs elected to resubmit the BLA on March 31 without hearing back from the agency. ¶ 142. Y-mAbs confirmed the resubmission in a press release on April 1, 2022, in which Gad stated that he was "excited to see the completion of Y-mAbs' second BLA submission in neuroblastoma." ¶ 143. The press release did not disclose that Y-mAbs resubmitted the BLA without getting the FDA's approval.

On April 27, 2022, Y-mAbs announced that Møller had stepped down as CEO and that Gad would switch from Board Chairman to interim CEO. ¶ 147. On May 10, 2022, during a conference call, Gad stated that Y-mAbs was "thrilled with our recent resubmission of the omburtamab BLA" and that the "pre-BLA meeting with the FDA in January of this year" had "confirmed our path towards our March BLA resubmission, which we ultimately achieved." ¶ 149. Gad added that Y-mAbs was "hopeful that omburtamab will be approved given the meaningful improvements in overall survival rate, which data has significantly matured with time." *Id.*

During an earnings call on August 9, 2022, Gad stated that "[w]e are optimistic about the potential approval based on meaningful improvement in overall survival rates and unparalleled efficacy in patients with CNS metastases from neuroblastoma." ¶ 151. On the same call, Rajah stated that "the headline news around efficacy concludes that there is a clear . . . clinical benefit in terms of response rates and survival with a manageable safety profile." ¶ 152. Rajah also provided a description of the results of Study 03-133 and Study 101 and stated that "I think combined with

these 2 studies, we believe that there is clearly a signal of clinical benefit for these patients who really have no alternative treatments, with a very poor prognosis." *Id.* He also stated that the team was "confident we are able to address these, not just the clinical arguments, but also the statistical arguments with a high degree of confidence." *Id.*

On October 26, 2022, the FDA publicly released a Briefing Document for a meeting of the Oncologic Drugs Advisory Committee (ODAC) scheduled for October 28, 2022. ¶ 154. The Briefing Document identified various issues with Y-mAbs's BLA submission, "highlighted the fact that FDA had repeatedly warned Y-mAbs over the course of years" about some of these issues, and "emphasized that Y-mAbs never received approval from FDA to resubmit the BLA." ¶¶ 155–157. Y-mAbs common shares fell from a closing price of $15.17 a share on October 25, 2022, to$11.01 on October 26, 2022. ¶ 162. The shares were trading at $8.93 on October 28, 2022, when trading was halted for the ODAC meeting. ¶ 163.

On October 28, 2022, Y-mAbs filed a Form 8-K with the SEC informing investors that the Advisory Committee had voted unanimously, 16–0, that Y-mAbs had not provided sufficient evidence to conclude that omburtamab improved overall survival. ¶ 164. By October 31, 2022, Y-mAbs common shares had fallen to $3.61 a share. ¶ 166.

II. Procedural History

Robert Corwin filed this class action lawsuit on January 18, 2023. Dkt. 1. After several lead plaintiff applications were received, the Court appointed Miramontes in April 2023. Dkt. 34. Miramontes then filed an amended complaint. Dkt. 38. The amended complaint alleges that Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5, and that Gad and Møller violated Section 20(a) of the Exchange Act. ¶¶ 183–201.

The amended complaint alleges that many statements were materially false or misleading. *See* ¶¶ 92–94 (Oct. 5, 2020 press release), ¶¶ 95–101 (Oct. 6, 2020 call), ¶ 102 (Oct. 6, 2020 submission), ¶ 107, 109 (Nov. 6, 2020 call), ¶ 115, 117 (Feb. 26, 2021 call), ¶ 122 (June 23, 2021 press release), ¶ 127 (Nov. 5, 2021 call), ¶ 129 (Dec. 15, 2021 presentation), ¶ 133 (Feb. 11, 2022 press release), ¶ 137–138 (Feb. 25, 2022 call), ¶ 143 (Apr. 1, 2022 press release), ¶¶ 148–149 (May 10, 2022 call), ¶¶ 151–152 (Aug. 9, 2022 call).

LEGAL STANDARDS

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint need not contain "detailed factual allegations," but must include "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In resolving a motion to dismiss, the Court accepts as true all well-pled factual allegations and draws all reasonable inferences in the plaintiff's favor. *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

"Securities fraud claims are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss." *Id.* at 99. Specifically, the amended complaint must meet the heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 (PSLRA). *See ECA & Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009).

Under Rule 9(b), "a securities fraud claim based on misstatements must identify: (1) the allegedly fraudulent statements, (2) the speaker, (3) where and when the statements were made, and (4) why the statements were fraudulent." *In re PetroChina Co. Ltd. Sec. Litig.*, 120 F. Supp. 3d 340, 353–54 (S.D.N.Y. 2015) (citing *Anschutz Corp. v. Merrill Lynch & Co., Inc.*, 690 F.3d 98, 108 (2d Cir. 2012)). Under the PSLRA, the complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).

In addition, the PSLRA requires that a complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2)(A). "The requisite state of mind in a Rule 10b-5 action is an intent to deceive, manipulate or defraud. In this Circuit, plaintiffs can satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *Setzer v. Omega Healthcare Invs., Inc.*, 968 F.3d 204, 212 (2d Cir. 2020) (cleaned up). "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 324 (2007).

I. Elements of Section 10(b) Claim

Section 10(b) makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). Rule 10b-5, the SEC's implementing rule, provides that it is unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5. "To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must plead: (1) a misstatement or omission of material fact; (2) scienter; (3) a connection with the purchase or sale of securities; (4) reliance; (5) economic loss; and (6) loss causation." *Arkansas Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 351–52 (2d Cir. 2022).

A. Material Misrepresentation or Omission

To adequately allege a material misrepresentation, a plaintiff must allege particularized facts showing that the statement "was false *at the time it was made*." *In re Bristol-Myers Squibb Co. CVR Secs. Litig.*, 658 F. Supp. 3d 220, 230 (S.D.N.Y. 2023) (citation omitted). And since there is no affirmative duty to disclose all material information, an omission is actionable only if disclosure was necessary "to make . . . statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b); *see also Shapiro v. TG Therapeutics, Inc.*, 652 F. Supp. 3d 416, 421 (S.D.N.Y. 2023) ("[A]lthough Rule 10b-5 imposes no duty to disclose all material, nonpublic information, once a party chooses to speak, it has a duty to be both accurate and complete." (internal quotation marks omitted)).

"The standard of materiality is whether the omitted fact 'would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.'" *Shapiro*, 652 F. Supp. 3d at 421 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988)). "[B]ecause of the fact-intensive nature of the materiality inquiry, the Court may not dismiss a complaint 'on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance.'" *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 528 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016) (quoting *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 235 (2d Cir. 2014)).

1. Forward-Looking Statements

The PSLRA amended the Securities Act and the Exchange Act to establish "a statutory safe-harbor for forward-looking statements." *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 765 (2d Cir. 2010). Forward-looking statements include "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer" or "any statement of the assumptions underlying or relating" to those plans or objectives. 15 U.S.C. § 78u-5(i)(1)(B), (D). "[A] defendant is not liable if the forward-looking statement is identified and accompanied by meaningful cautionary language *or* is immaterial *or* the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." *Slayton*, 604 F.3d at 766.

"[B]ecause the safe harbor specifies an 'actual knowledge' standard for forward-looking statements, 'the scienter requirement for forward-looking statements is stricter than for statements of current fact. Whereas liability for the latter requires a showing of either knowing falsity or recklessness, liability for the former attaches only upon proof of knowing falsity.'" *Id.* at 773 (quoting *Inst. Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 274 (3d Cir. 2009)).

2. Opinion Statements

"[O]pinions are not actionable unless either (i) the speaker did not subjectively believe the opinion; (ii) the opinion contained one or more embedded factual statements that was false; or

(iii) the statement failed to provide 'critical context,' meaning that the speaker implied he or she had a reasonable basis for the opinion but in fact did not." *Shapiro*, 652 F. Supp. at 423 (quoting *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 175 (2d Cir. 2020)). "[T]he appropriate perspective for identifying whether a statement of opinion implies facts is that of the reasonable investor." *Abramson*, 965 F.3d at 175. "In assessing what a reasonable investor would expect, the Supreme Court stressed the importance of context, such as 'the customs and practices of the relevant industry' and whether the opinion was expressed in a formal statement such as an S.E.C. filing or instead was a 'baseless, off-the-cuff judgment[ ], of the kind that an individual might communicate in daily life.'" *Id.* (alteration in original) (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 190 (2015)).

B. Scienter

As noted above, "a complaint must, with respect to each defendant and with respect to each act or omission alleged to constitute securities fraud, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Bristol-Myers*, 658 F. Supp. 3d at 230 (cleaned up); *see also* 15 U.S.C. § 78u-4(b)(2). "For an inference of scienter to be strong, 'a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged.'" *ATSI*, 493 F.3d at 99 (alterations in original) (quoting *Tellabs*, 551 U.S. at 324).

C. Loss Causation

"Loss causation is the causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005) (internal quotation marks omitted). "[T]o establish loss causation, a plaintiff must allege that the subject of the fraudulent statement or omission was the cause of the actual loss suffered, *i.e.*, that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Id.* at 173 (cleaned up).

II. Elements of Section 20(a) Claim

To state a claim under section 20(a) of the Exchange Act, "a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *Carpenters*, 750 F.3d at 236 (internal quotations omitted). "If a plaintiff has not adequately alleged a primary violation, i.e., a viable claim under another provision of the Exchange Act, then the § 20(a) claims must be dismissed." *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 577 (S.D.N.Y. 2016).

DISCUSSION

I. Section 10(b) Claim

The amended complaint covers a number of allegedly false or misleading statements. They all fall within the following categories: (1) statements regarding the timing of the BLA resubmission; (2) statements regarding progress toward that resubmission; (3) statements interpreting the FDA's feedback and guidance to Y-mAbs about the BLA, and (4) statements interpreting clinical data. As described below, a subset of Defendants' statements interpreting the FDA's feedback and guidance are actionable.

A. The Alleged Statements

1. Statements regarding timing of resubmission.

The first category encompasses statements concerning Y-mAbs's timeline for resubmission of the BLA. The statements reflect an initial estimate of resubmission by late 2020 or early 2021, Am. Compl. ¶¶ 94, 95, 99, 107, and later an amended estimate of early 2022, ¶¶ 127, 133, 137. Miramontes says that these statements were false or misleading because Defendants promised to address all of the FDA's concerns prior to resubmission and Defendants knew that wouldn't be possible on this resubmission timeline. Dkt. 44 at 15. Defendants argue that "[s]tatements regarding the timing for resubmission of the BLA are squarely protected by the PSLRA safe harbor for forward-looking statements." Dkt. 40 at 15.

These statements cannot serve as a basis for a section 10(b) claim. The statements are forward looking and are not accompanied by allegations supporting Defendants' actual knowledge that the statements were false or misleading at the time they were made. *See Shapiro*, 652 F. Supp. 3d at 423–24 (finding the defendants statement that we "expect this year to complete our BLA submission" are "protected by the PSLRA's safe harbor for forward-looking statements").

Moreover, in *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016), the Second Circuit affirmed the dismissal of section 10(b) claims based on statements that the defendants "expect[ed] a decision on [the drug] by the end of the year." *Id.* at 213 (first alteration in original). The Court reasoned that these statements "did not conflict with the information available to them at the time" and were ultimately correct since the FDA did provide a decision rejecting the drug by the end of the year. *Id.* Here too, the statements did not conflict with available information on the timing of resubmission and some of the statements turned out to be true: according to Miramontes's allegations, the resubmission occurred in March 2022. ¶ 142.

Miramontes claims that these statements created the false impression that Defendants would reach agreement with the FDA by those deadlines. Dkt. 44 at 15. But Defendants never made such a promise. Miramontes relies on statements in which Møller stated that Y-mAbs "hope[d] to reach a final agreement" or "expect[ed] to get a green light" at upcoming meetings. Am. Compl. ¶ 115, 129. But just as in *Tongue*, these aspirational statements about timing and what

Defendants expected to happen in the future—whether best understood as opinions or forward-looking statements—were not misleading about any facts on the ground. *See Tongue*, 816 F.3d at 212–13.

2. Statements regarding progress towards resubmission.

The next category comprises statements concerning the progress toward resubmission. This includes statements that Defendants were "surprised" and "disappointed" by the initial RTF letter, Am. Compl. ¶ 96; "confident" they could "address all points raised by the FDA," ¶¶ 93, 95, 107, 115, or otherwise "rectify" the issues, ¶ 97; and "excited" about resubmission and "hopeful" or "optimistic" about approval given the drugs "meaningful improvements in overall survival rate" and efficiency, ¶¶ 143, 149, 151. Defendants similarly stated that resubmission was "progressing well" or "as planned," ¶ 127, 137; and (in 2022) that resubmission had occurred "as promised," ¶ 148. This category also includes statements that the FDA "want[ed] to work with" Y-mAbs on resubmission, ¶ 98, and that Y-mAbs was "pleased to be aligned with the FDA on the next steps," ¶¶ 122, 127, 137.

At the outset, these statements convey opinions. Miramontes claims that they are "statements of fact" because they do not all contain qualifiers like "I believe." Dkt. 44 at 16. But the Second Circuit has analyzed similarly broad statements as opinions, even when they are not accompanied by such qualifiers. *See Tongue*, 816 F.3d at 211 (describing as opinions the defendants' statements that they were "satisfied with where the progress is going" and were feeling "relaxed" and "pleased"); *see also Gillis*, 197 F. Supp. 3d at 589 (concluding that the defendant's statements that it was "surprised" by the FDA's decision, "encouraged" by the FDA's feedback, and "confident" that a drug would receive FDA approval were all opinions).

Miramontes also argues that the statements, even if understood as opinions, are nevertheless actionable because "Defendants omitted information whose omission makes the statement misleading to a reasonable investor." Dkt. 44 at 16 (cleaned up). In *Omnicare*, the Supreme Court acknowledged that "a reasonable investor may, depending on the circumstances, understand an opinion statement to convey facts about how the speaker has formed the opinion—or, otherwise put, about the speaker's basis for holding that view. And if the real facts are otherwise, but not provided, the opinion statement will mislead its audience." 575 U.S. at 188. Miramontes argues that this is the case here because Defendants' "positive statements" belie the true feedback it was receiving from the FDA and create the impression that the FDA meetings were all positive. Dkt. 44 at 16.

But the Second Circuit has already rejected this application of *Omnicare*. In *Tongue*, the Second Circuit affirmed the district court's dismissal of the plaintiffs' section 10(b) claims related to the defendants' statements about the FDA's timeline for approving their drug. *See* 816 F.3d at 203. The defendants made statements "estimating a 90% likelihood of achieving the Approval Milestone and projecting FDA approval in late 2012." *Id.* at 211. The Second Circuit held that these statements were not actionable, despite the plaintiffs' arguments that they were "materially

misleading" under *Omnicare* because they "fail[ed] to disclose the FDA's repeated statements of concern about the use of single-blind studies." *Id.* The Court reasoned that there was "no plausible allegation that the FDA's interim feedback conflicted with any reasonable interpretation of Defendants' statements about FDA approval" because the "statement[s] of optimism" were consistent with the FDA's guidance about how deficiencies could be overcome. *Id.* In addition, the plaintiffs were "sophisticated investors" who would be aware that "Defendants and the FDA were engaged in a dialogue . . . about the sufficiency of various aspects of the clinical trials and that inherent in the nature of a dialogue are differing views." *Id.* "That such a dialogue was ongoing did not prevent Defendants from expressing optimism, even exceptional optimism, about the likelihood of drug approval." *Id.*

The Second Circuit also stated that, under *Omnicare*, "Defendants need not have disclosed the FDA feedback merely because it tended to cut against their projections." *Id.* at 212. Even though a plaintiff would have clearly "been interested in knowing about the FDA feedback, and perhaps would have acted otherwise had the feedback been disclosed . . . *Omnicare* does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion expressed in the registration statement." *Id.*

As in *Tongue,* Defendants here expressed optimism about approval while failing to disclose the FDA's warnings about use of a single-arm study or other concerns that the FDA voiced about Defendants' methods for interpreting the data. But Miramontes does not allege that the FDA ever stated that approval of omburtamab was unlikely. Nor does Miramontes allege that the FDA indicated that there was no road to successful resubmission. To the contrary, the amended complaint demonstrates that the FDA continued to meet with Y-mAbs and provide feedback on steps that the company should take to move toward successful submission. "Thus, fatal to Plaintiff['s] case is the absence of any serious conflict between the FDA's interim, albeit repeated, concerns about methodology and Defendants' optimism about FDA approval." *Id.* Defendants' statements are not materially misleading just because they did not "include a fact that would have potentially undermined" their optimism. *Id.*

Absent any clearer conflict between the FDA's feedback and Defendants' statements, opinions expressing optimism that resubmission was "progressing well" or that Defendants were "hopeful" or "confident" are not actionable under section 10(b). *See Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 173–74 (2d Cir. 2020) (affirming dismissal of section 10(b) claims based on "Defendants' descriptions of the Phase 2 results as 'encouraging' and 'an improvement'" because "[g]eneric, indefinite statements of corporate optimism typically are not actionable" unless "the speaker knew that the contrary was true" (internal quotation marks omitted)); *In re EDAP TMS S.A. Sec. Litig.*, 2015 WL 5326166, at *12 (S.D.N.Y. Sept. 14, 2015) (dismissing section 10(b) claims based on statements that FDA review process was "on track" because "insofar as these statements place a positive spin on developments in the PMA process, they constitute inactionable puffery and corporate optimism"); *In re AstraZeneca plc Sec. Litig.*, 2022 WL 4133258, at *8

(S.D.N.Y. Sept. 12, 2022), *aff'd sub nom. Nandkumar v. AstraZeneca PLC*, 2023 WL 3477164 (2d Cir. May 16, 2023) (same).

Finally, to the extent that Miramontes relies on the description of omburtamab as having "meaningful improvements in overall survival rate" and efficacy, this characterization of the drug is "not misleading simply because the FDA disagreed with Defendants' interpretation of the data." *Tongue*, 816 F.3d at 214.

3. Statements interpreting feedback and guidance.

The statements in the next category also concern the progress towards resubmission but go a step further by commenting on or summarizing the FDA's interim feedback or guidance and/or Y-mAbs's compliance with the FDA's requests. These statements are:

- On October 5, 2020, Y-mAbs published a press release stating that "[u]pon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control ('CMC') module and the Clinical module of the BLA require further detail. No additional non-clinical data have been requested or are required." Am. Compl. ¶ 92. This press release was attached to the company's Form 8-K filed the next day. ¶ 102.
- During a conference call on October 6, 2020, Møller reiterated that "no additional nonclinical data" had been "requested" or was "required." ¶ 95. He also stated that the FDA "requested 2 things," namely "a different type of statistical comparison between the data from Study 03-133 and the old study with more than 100 patients and the historical controls" and "tumor response data for patients from Study 101, where the tumor responses has been independently evaluated according to the RANO criteria for measuring tumor responses in the central nervous system." ¶ 100. Møller stated that these requests were "not a problem," "[w]e can do it," "we have everything," and that he had "no concern that the FDA will think, 'Oh, that is not sufficient response.' I think we are beyond that also." ¶ 100. He added that the denial was a "minor setback." ¶ 101.
- During Y-mAbs's earnings call on November 6, 2020, Møller stated that it's "pretty clear that on the Chemistry, Manufacturing, and Controls we have resolved all the issues that they have requested." ¶ 107. Gad also stated that there were "still some issues we need additional clarification on" and that Y-mAbs was "still discussing it" with the FDA. Dkt. 41-4 at 12.
- During a presentation on December 15, 2021, Møller stated that "I think we have put together a very strong package that should satisfy the concerns the FDA raised [in the RTF letter] and that they have also raised during our discussions." ¶ 129.
- On February 11, 2022, Y-mAbs issued a press release, in which Gad is quoted as stating that a pre-BLA meeting had provided "a clear regulatory path forward for the resubmission of the BLA." ¶ 133.
- During an earnings call on February 25, 2022, Gad stated that Y-mAbs "held a pre-BLA meeting with the FDA in January, which confirmed our path towards a BLA resubmission in March." ¶ 137. On the same call, Møller stated, "To the best of my understanding, all the information that we need, we have. . . . The FDA wants to

understand how they can actually – to which degree they can verify the historical control data in the central German cancer registry in Cologne, but that's not something that is holding up the submission of the BLA filing." ¶ 138.

- On May 10, 2022, during a conference call, Gad stated that a "pre-BLA meeting with the FDA in January of this year" had "confirmed our path towards our March BLA resubmission, which we ultimately achieved." ¶ 149.

At the outset, Miramontes cannot rely on statements of general corporate optimism such as "we can do it" or that the BLA denial was a "minor setback." For the reasons stated in Section I.A.2, these opinion statements are not actionable absent a showing that they conflict with interim feedback from the FDA. Miramontes has not identified any such conflict, instead arguing only that these statements do not disclose all portions of the FDA's concerns. This is not sufficient.

What remains are statements that Defendants had in their possession all the information the FDA requested or had resolved all the concerns raised by the FDA. *See* ¶¶ 92, 95, 100, 102, 107, 129, 133, 137, 138, 149. Even if these are understood as statements of opinion, Miramontes has plausibly alleged conflicts between these statements and the FDA's immediately preceding feedback that would make these statements materially misleading.

First, on October 5, 2020, Møller stated that the FDA had not "requested" or "required" any "additional non-clinical data." ¶¶ 92, 102. And on October 6, 2020, Møller reiterated that no "additional nonclinical data have been requested or are required" and stated that Y-mAbs has "everything" for resubmission. ¶¶ 95, 100. According to Miramontes, these statements were "false because, for example, FDA required the submission to include a comparison of patients that received craniospinal irradiation but zero CGCCR patients received that treatment." Dkt. 44 at 13. So Y-mAbs would need additional data to respond to the FDA's request.

Second, Gad's stated on November 6, 2020, that Y-mAbs had "resolved all the issues" the FDA raised, ¶ 107, but during a meeting only three days earlier the FDA "had confirmed that the deficiencies in the CGCCR data persisted," Dkt. 44 at 14.

Third, Møller's statement that he thought Y-mAbs had put together a package that satisfied the FDA's concerns, Am. Compl. ¶ 129, directly conflicts with the statements by the FDA on September 14, 2021, that it had "outstanding concerns regarding the datasets, definitions and derivations of the variables," ¶ 126.

Fourth, Gad's three statements that meetings with the FDA had provided "a clear regulatory path forward for the resubmission" or had "confirmed our path towards" resubmission, ¶¶ 133, 137, 149, are actionable because the FDA continued to voice concerns with the available data, including stating that there was "insufficient information to provide agreement on the efficacy package to support the BLA," ¶ 133. These statements misrepresent the contents of the meetings with the FDA. And they become more problematic when viewed in full context. To give an example, Gad's statement in May 2022 that the FDA had in January "confirmed our path" came

after the BLA had been resubmitted, and with no disclosure that the company had decided *not* to await final agreement with FDA before doing so. ¶ 149.

Finally, Møller's statement on February 25, 2022, that "all the information that we need, we have," and any outstanding concerns were not "holding up the submission of the BLA filing," ¶ 138, were contradicted by the FDA's statements on January 13, 2022, that Y-mAbs had still provided "insufficient information" and that the FDA's outstanding concerns "would be a filing issue," ¶ 131.

Unlike statements about "confidence" in resubmission or "alignment" with the FDA, these statements are not forward-looking and do not convey general notions of optimism regarding the prospect of future approval. Instead, they describe the current state of the resubmission material in ways that plausibly contradict the FDA's immediately preceding feedback on that same material. *See Abramson*, 965 F.3d at 178 (concluding that statements of opinion describing the outcome of a drug study were actionable because a "jury could conclude that the sheer volume of competing facts required the defendant "either to speak less confidently" about the results or "to disclose the existence of" contrary information); *Shanawaz v. Intellipharmaceutics Int'l Inc.*, 348 F. Supp. 3d 313, 324–25 (S.D.N.Y. 2018) (finding actionable "Defendants' allegedly false descriptions of the contents of the NDA itself" and distinguishing such descriptions from "Defendants' opinions about the NDA's prospects before the FDA").

Defendants say that these statements are not actionable because "interim feedback is not material." Dkt. 40 (quoting *Sanofi*, 87 F. Supp. 3d at 528). That might be true in some cases, but as always, "context is important." *Sanofi*, 87 F. Supp.3d at 539. And "because of the fact-intensive nature of the materiality inquiry, the Court may not dismiss a complaint 'on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance.'" *Id*. at 528 (quoting *Carpenters*, 750 F.3d at 235). Here, Defendants made several public statements concerning the back-and-forth with the FDA, which indicates that *Defendants* themselves understood that the FDA's feedback was material. Having done this, Defendants were not permitted to disclose this interim feedback in a partial and misleading manner. *See In re Vivendi Sec. Litig.*, 838 F.3d 223, 258 (2d Cir. 2016) ("[O]nce a company speaks on an issue or topic, there is a duty to tell the whole truth." (citation omitted)). The Court cannot conclude at this stage that the omitted information was "so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance.'" *Sanofi*, 87 F. Supp.3d at 528 (quoting *Carpenters*, 750 F.3d at 235).

Miramontes has therefore plausibly alleged that these statements were materially false or misleading.

4. Statements interpreting clinical data.

The final category covers statements by Defendants interpreting clinical-trial data. These statements are:

- Møller's statement on November 6, 2020, commenting on interim results for 17 Study 101 patients. Møller specifically stated that the study's overall survival rate "compares very favorably to an OS of approximately 30% in a historical control group" and the preliminary data is "encouraging." Am. Compl. ¶ 109.
- Møller's statement on February 26, 2021, regarding "a new paper published by SIOPEN" which provided "some more granularity and details on that database than there was available initially from the central German cancer registered database" and provided a second set of historical controls. ¶ 117. Møller further stated that "the FDA seems to be very happy" that Y-mAbs had this additional data. *Id.*
- Rajah's statement on August 9, 2022, that there is a clear "clinical benefit in terms of response rates and survival" and interpreting Study 03-133 and Study 101. ¶ 152.

Miramontes claims that these statements were "materially false and misleading" because Defendants "knew or recklessly disregarded but failed to disclose" various concerns that the FDA had raised regarding Study 101 and Study 03-133. *See* ¶¶ 103, 109, 118, 153. Contrary to Miramontes's arguments, these statements are not actionable.

First, "Defendants' statements were not misleading simply because the FDA disagreed with Defendants' interpretation of the data." *Tongue*, 816 F.3d at 214. None of these statements claims that the FDA had similarly interpreted the studies at issue. And Miramontes never alleges that "Defendants' interpretation of the data was irrational or unreasonable." *Id.* So Miramontes cannot base a section 10(b) claim on reasonable interpretations of data simply because the FDA did not ultimately adopt those same interpretations.

Second, Rajah's statement *did* disclose many of the FDA's concerns over the data. The amended complaint quotes the portion of Rajah's statement that "we have been involved in a number of discussions – ongoing discussions with the FDA" and that "[we] are confident we are able to address these, not just the clinical arguments, but also the statistical arguments with a high degree of confidence." ¶ 152. But Miramontes fails to quote the preceding portion of Rajah's statement disclosing a number of "important points" that had been "brought up in previous discussions with the FDA." Dkt. 41-11 at 13. These included that "Study 03-133 is a single arm, single center trial" and "relies on comparisons with the external control data, which always has limitations . . . to serve as an appropriate comparator when you're trying to show incremental treatment effects and survival improvements." *Id.* Rajah also disclosed that, as to Study 101, "this is still a relatively small study" and Y-mAbs therefore "anticipate[d] there w[ould] be questions around the number of patients with measurable disease" and "whether the degree of confidence in the responses seen can be replicated in a larger patient population." *Id.* And Rajah qualified his statement of optimism by explaining that omburtamab was treating "a rare disease, in an area of

unmet medical need with very poor prognosis," so Y-mAbs "believe[d] the FDA and the AdCom will look at this as an area where flexibility needs to be applied in making any judgment around risk benefit assessment." *Id.* at 13–14.

Finally, Møller's description of the FDA as "very happy" about the new data is not actionable for the reasons stated in Section I.A.2. At best, the amended complaint seems to suggest that the new data would not be enough to meet all the FDA's concerns. *See* Am. Compl. ¶ 112 (stating that the new data did not include data on post-CNS release). But Miramontes has not identified any allegations suggesting that the FDA was disappointed or otherwise not "very happy" that Y-mAbs had a new data source.

* * *

Because none of the actionable statements was made by Rajah and there are no allegations that Rajah had ultimate authority over any of the other statements, he cannot be held liable under Section 10(b). *See Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 142–43 (2011).

B. Scienter

Defendants also argue that, if any statements are actionable, the amended complaint should still be dismissed for failure to adequately plead scienter. Dkt. 40 at 20. Miramontes "may satisfy this [scienter] requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI*, 493 F.3d at 99. Defendants argue that Miramontes has not adequately alleged motive and opportunity. Dkt. 40 at 20–21. But Miramontes claims that he satisfies the scienter requirement by showing strong circumstantial evidence of conscious misbehavior or recklessness because Defendants "spoke in detail about the RTF letter, their meetings with FDA and the SIOPEN data" and provided inaccurate information regarding the FDA's concerns, despite being aware of the truth. Dkt. 44 at 22.

To show recklessness, it "is sufficient for [plaintiffs] to allege 'defendants' knowledge of facts or access to information contradicting their public statements.'" *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 40 (2d Cir. 2000) (quoting *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000)). Here, that standard is met. Y-mAbs was responsible for submitting the BLA and updated material to the FDA, and omburtamab was the company's "lead product candidate" during the Class Period. Am. Compl. ¶¶ 5, 32. In addition, the amended complaint pleads that Gad and Møller were actively involved in the omburtamab BLA, ¶¶ 26–28, and are quoted in the amended complaint as providing detailed statements on behalf of Y-mAbs on the progress of the BLA and discussions with the FDA, *see, e.g.*, ¶¶ 95–101, 120, 152. The amended complaint also alleges that Gad "had actual knowledge and supervision over Y-mAbs's communications with FDA and the true (undisclosed) facts concerning FDA approval process," including by attending the meeting on October 28, 2022 with the FDA, ¶ 26; and that Møller "had actual knowledge and supervision over Y-mAb[s]'s communications with FDA," ¶ 27. Based on these allegations, Defendants would have

known that their public statements were false. *See Shanawaz*, 348 F. Supp. 3d at 326. In addition, because Møller was the CEO of Y-mAbs during the relevant period and Gad is the founder, President, interim CEO, and Head of Business Development and Strategy, the scienter of Møller and Gad can be imputed to Y-mAbs. *See Jackson v. Abernathy*, 960 F.3d 94, 98–99 (2d Cir. 2020).

At the motion to dismiss stage, Miramontes has "establish[ed] that these Defendants 'knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation.'" *Shanawaz*, 348 F. Supp. 3d at 326 (quoting *Novak*, 216 F.3d at 308).

C. Loss Causation

Finally, Defendants claim that Miramontes has not pleaded loss causation. "To plead loss causation, a plaintiff must allege that it purchased securities at an inflated price and that the price dropped once the fraud became known." *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 336 (S.D.N.Y. 2014) (citing *Acticon AG v. China N.E. Petroleum Holdings Ltd.*, 692 F.3d 34, 40 (2d Cir. 2012)). The amended complaint alleges that "[o]n October 26, 2022, shortly after the market opened, FDA publicly released its Briefing Document for the Oncologic Drugs Advisory Committee Meeting scheduled for October 28, 2022." Am. Compl. ¶ 154. The Briefing Document "identified the deficiencies" in Defendants' submissions and "highlighted the fact that FDA had repeatedly warned Y-mAbs" about these deficiencies, including in tables "summarizing the numerous communications with Y-mAbs." ¶¶ 155–156. The amended complaint further alleges that Y-mAbs's stock price fell from $15.17 to $11.01 per share that day. ¶ 162. It fell to $8.85 by the next day and was "trading at $8.93 on October 28, 2022 when trading was halted for the Advisory Committee." ¶ 163.

Defendants claim that Miramontes has not alleged loss causation because "the FDA Briefing Document did not correct any prior disclosures in any of the challenged statements." Dkt. 40 at 24. So any subsequent decline in the stock price could not have been causally linked to any disclosure of fraud. Defendants' argument falls flat as to the statements the Court has deemed actionable. As explained above, each statement appears to contradict a warning by the FDA and these warnings are made clear in Table 3 of the FDA Briefing Document, which was released just before the stock price fell. *See* Dkt. 38-1 at 22–23. As with the other elements of his claims, Miramontes will need to prove loss causation at trial. But he has alleged enough to overcome Defendants' motion to dismiss.

II. Section 20(a) Claim

Defendants argue that the Section 20(a) claims should be dismissed against Møller and Gad for the same reasons that the Section 10(b) claims should be dismissed. As explained, Miramontes has adequately alleged a primary violation of Section 10(b) based on certain statements by Møller and Gad. And, as already explained, Møller and Gad were each a "decision-making official who made an allegedly fraudulent statement about [omburtamab]. Each also had, as previously discussed, knowledge of or access to the omitted facts that allegedly rendered his

statements misleading, and thus for the purposes of the pleading stage engaged in conduct that may constitute recklessness." *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 572 (S.D.N.Y. 2011). So Defendants' motion to dismiss the Section 20(a) claims is denied to the extent that those claims are based on statements the Court has held actionable.

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is GRANTED IN PART and DENIED IN PART. The motion is denied with respect to Miramontes's Section 10(b) and 20(a) claims based on the statements and omissions in paragraphs 92, 95, 100, 102, 107, 129, 133, 137, 138 and 149 of the amended complaint. The motion is otherwise granted.

The Clerk of Court is directed to terminate ECF No. 39 and dismiss Defendant Vignesh Rajah from the case.

SO ORDERED.

Dated: February 5, 2024
New York, New York

ARUN SUBRAMANIAN
United States District Judge